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| 24998 | 7590 | 06/08/2005 | EXAMINER | |
| DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP | | | GAKH, YELENA G | |
| 2101 L Street, NW | | | ART UNIT | |
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1743

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/858,477

Applicant(s)

SEKINE ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/24/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. RCE filed on 04/25/05 is acknowledged. Claims 1-12, 14-17 and 39 are pending in the application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12, 14-17 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7, 12 and 39 recite, "providing a first data set containing substances". Such expression may assume a set that physically contains chemical compounds, which is not the case. The specification refers to 'a first data set [or *database*, which is more appropriate term] of compositions of said chemical materials', which is a much clearer definition. The expression a "data set containing substances" is not a clear and definite expression. If the composition of the materials is only one of the embodiments, then other embodiments should be indicated as a Markush group to make this expression clear and definite. Moreover, it is not clear, what does it mean controlled substances of the same compound group? What does "the same compound group" mean? Is this the same class of compounds? Does it mean that the compounds have similar properties? Similar toxicity? No clear definition for such group is given in the specification.

Claims 3, 9 and 15 it is not clear, what "the source of control" might be, and how it is related to all other data sets of the parent claims.

Claim 14 recites a limitation "said substance", which lacks an antecedent basis, since the parent claim recites "substances". Moreover, the parent claim recites two types of substances: substances comprising the chemical materials, and controlled substances. It is not clear, which substance is recited in claim 14?

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In claims 3, 9 and 15 it is not clear, what “the source of the control” is, and therefore it is not clear, what is its control object code?

Claim 6 recites “obtaining said data sets from an outsourcing company”, while the parent claim recites “providing data sets”. If “providing data sets” means “obtaining said data sets from outsourcing company”, does it mean that this should be the outsourcing company that provides these data? If this is the outsourcing company that provides the data, then how can the steps of the parent claim be active steps performed by the routineer in the art?

Claim 12 is not clear as to which specific controlled substances are categorized by a group control ID. If these are not all controlled substances of the first set, then what is the principle of choosing compounds for the second data set in order to categorize them by the group control ID?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-12, 14-17 and 39** are rejected under 35 U.S.C. 102(b) as being anticipated by Sturgeon et al. (US 5,664,112).

Sturgeon teaches a method of integrated Hazardous Materials Management (HMM), providing database for materials containing hazardous compounds and grouping controlled (hazardous) substances by Hazardous Materials Index. “The HMM grouping 21 monitors consumption of chemicals and chemical mixtures, using process definitions and using manual drawdown for non-process consumption. Process definitions cover all chemicals used as input materials for a given process. Process templates provide users with reusable process definitions and with process run parameters such as process run date and frequency of use. Chemical emissions, outfalls and by-product wastes are tracked as they arise by the HPM [Hazardous Permit Management] and HWM [Hazardous Waste Management] groupings 31 and 51. The

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HMM grouping 21 can generate in-house chemical transfer and usage reports and mass balance reports" (col. 12, lines 21-31). Process templates intrinsically provide ratio of discharge and emission quantity of hazardous compounds. HMM includes handling precautions, hazards and legal regulations with the databases provided by an outsourcing company (Figures 1-2).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 1-12, 14-17 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Leal et al. (US 5,311,437, IDS).

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Leal teaches a method for management of chemical materials, comprising providing data sets containing controlled (hazardous) substances, “identification of the physical character of the material, identification of a procedure in which the material is operable, and a hazard/environmental assessment. The selector tool further includes selection means executable by the digital processor for controllably selecting, and optionally displaying in a preselected manner that is useful in making a materials selection decision, a material from the data base responsive to a comparison with the physical character of the material, the procedure identification, the end-product specifications, the product/performance risk, or the hazard/environmental assessment. The selection may also be made on other factors such as end product specification and product performance risk” (col. 2, lines 43-59).

While Leal does not specifically indicate grouping compounds and providing them a common control group ID, it would have been obvious for any person of ordinary skill in the art to do so, because it helps manage compounds with e.g. the same toxicological properties. While Leal does not specifically indicate a control object code for designating the source of control, it would have been obvious to do so, because this facilitates managing manufacturing facilities.

Response to Arguments

10. Applicant's arguments filed 01/25/05 have been fully considered but they are not persuasive.

While the amendment to the claims led to withdrawing some rejections under 35 U.S.C. 112, second paragraph, it raised other issues under the same paragraph.

While the Applicants argue that the database of material composition is a preferred embodiment, they do not provide a clear definition of what the first data set “containing substances” may comprise, since the data set is not a physical set of chemical compounds. From the applicants' explanations it is not clear as to what this data set refers.

Regarding the rejection over the prior art: the Applicants argue that while Sturgeon refers to a chemical identification and group 6 hazard category, he does not employ groups in the manner recited in amended claim 1. The examiner cannot agree with this. Sturgeon teaches: “the HMM grouping 21 can generate in-house chemical transfer and usage reports and mass

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balance reports" (col. 12, lines 21-31), which inherently provides ratio of discharge and emission quantity of hazardous compounds. HMM includes handling precautions, hazards and legal regulations with the databases provided by an outsourcing company (Figures 1-2). Therefore, Sturgeon groups compounds according to their chemical identification and hazard category, indicates the processes they participate in with corresponding yields, and include handling precautions, hazards, and legal regulations. The examiner considers Sturgeon's patent completely covering the subject matter of the claims in their present amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/6/05


YELENA GAKH
PRIMARY EXAMINER